DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

95133d

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECIEPT REQUESTED

December 14, 2004 W/L: 03-05

Richard Burns
Senior Vice President
TODDS, A Division of H. J. Heinz Company, L. P.
2450 White Road
Irvine, CA 92614-6250

Dear Mr. Burns:

On August 17-18, and 23, 2004, we inspected your seafood processing facility, located in Irvine, California. We found that you have a serious deviation from the seafood Hazard Analysis and Critical Control Points (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery product adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your cooked, ready-to-eat clam chowder packaged in a reduced oxygen/air, (i.e., hermetically sealed) plastic bag is adulterated, in that the clam chowder has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. You may find the Act, seafood HACCP regulation, and The Fish and Fisheries Products Hazards and Controls Guidance, *Third Edition*, published June 2001, through links in FDA's home page at www.fda.gov.

The deviation is as follows:

1. You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your HACCP plan for clam chowder does not list the food safety hazard(s) of *Clostridium botulinum* growth and toxin formation in your cooked

ready-to-eat clam chowder packed in reduced oxygen (i.e., hermetically sealed) plastic bags. In order to establish an effective plan to control *Clostridium botulinum* growth and toxin formation, you may wish to refer to Chapters 13, 16, 17 and 18, in addition to Table #A-4 of FDA's Fish & Fisheries Product Hazards & Controls Guidance, *Third Edition*. These chapters will provide specific information related to critical control points and critical limits to control *Clostridium botulinum* in reduced oxygen packages, including:

- Information on critical limits associated with adequate cook time(s) and temperature(s), in conjunction with information on continuous methods of monitoring to ensure maintenance of the cooking temperature throughout the entire process cook time.
- Information on critical control points associated with hot filling to ensure maintenance of adequate temperature(s) in order to reduce the potential for re-contamination during filling.
- Information on continuous transferring and filling systems that are completely enclosed to reduce the potential for re-contamination with airborne *Clostridium botulinum* spores.
- Information on a post packaging/filling critical control point to visually monitor the packaging seals/seams and perform destructive seal/seam examinations, in conjunction with monitoring residual chlorine in the cooling water.
- Information on a post processing critical control point for refrigerated storage.
- Information about placing a statement on the labels of your frozen reduced oxygen packaged products that instructs "keep frozen, thaw under refrigeration and use immediately after thawing."

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that corrections has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

If you any questions regarding this letter, please contact Ms. Mariza M. Jafary, Compliance Officer at 949-608-2977.

Your written reply should be directed to:

Pamela Schweikert
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Sincerely,

Alonza E. Cruse
District Director